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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,869	09/11/2003	Rebecca E. Cahoon	BB1294USCNT	6089

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/659,869	<b>Applicant(s)</b> CAHOON ET AL.	
	<b>Examiner</b> Medina A. Ibrahim	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I in the reply filed on 09/14/05 is acknowledged. The restriction is made FINAL.

New claims 17-29 are pending and are under examination.

### ***Sequence Listing***

Applicant's CRF and paper sequence listing have been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding SEQ ID NO: 36, or a nucleotide sequence encoding a polypeptide having at least 80%, 85% or 95% sequence identity to SEQ ID NO: 36 and having Myb-related transcriptional factor activity. The claims are also drawn to a vector, a recombinant DNA construct comprising said polynucleotide operably linked to a

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promoter, cell /plant/seed comprising said recombinant DNA, and a method of transforming a plant with said polynucleotide.

Applicant teaches isolated nucleotide sequences from various plant species including SEQ ID NO: 35 encoding SEQ ID NO: 36 from soybean. The specification states that the nucleotide sequence of SEQ ID NO: 35 encoding SEQ ID NO: 36 has Myb-related transcriptional factor activity, and can be used to regulate gene expression in transgenic plants. The specification, paragraph-bridging pages 1 and 2, states that plant Myb-related proteins have been shown to involve in a diversity of plant gene expressions, including expression of disease resistance genes, gibberellin-regulated genes, and stress-related genes. The specification also discloses domains that SEQ ID NO: 36 shares with a prior art Myb protein from *P. sativum* (Figure 1). The specification also teaches prophetic methods of transforming plants with SEQ ID NO: 35.

The state of the art, however, teaches that sequence homology alone is insufficient to determine the functional activity of a gene/protein. For example, an article from Science Journal (vol. 292, pp. 1486-1487, 2001, in record)) reveals genes encoding polypeptides that share an overall secondary structure and six domains of functional importance, which are still sufficiently divergent in that their function cannot be determined by sequence similarity alone.

Applicant does not teach any transcriptional factor activity by SEQ ID NO: 35 or 36 or disclose a transgenic plant with regulated gene expression as a result of expressing SEQ ID NO: 35. While Applicants are not required to provide empirical data to verify the Myb transcriptional activity by Applicants' SEQ ID NO: 36, a functional

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assignment based upon sequence alignments should be a starting point for determining a particular activity of a protein and should not replace empirical verification of a tentative functional assignment.

The state of the prior art also teaches that modification of gene expression or of phenotypic characteristics in plants by genetic transformation is highly unpredictable and hence significant guidance is required to practice the art without undue experimentation. One cannot predict the phenotypic effect or the agronomic benefit of SEQ ID NO: 35 when expressed in a transgenic plant. Moyano et al (The Plant Cell, Vol. 8, pp. 1519-1532 (1996)) teach six cDNAs encoding Myb proteins, Myb305, Myb306, Myb315, Myb330, and Myb340 isolated by sequence homology from *Antirrhinum* flowers. All sequences contained Myb domains for promoter activation. However, only one out of the six cDNAs had shown effect on the expression of a desired gene when expressed in yeast cells (see at least Results on pages 1521-1522).

Therefore, given the lack of guidance in the specification; the state of the prior art; the unpredictability inherent in gene regulation; and the lack of working examples, the claimed invention cannot be practiced without undue experimentation. Therefore, in view of the reasons set forth above, the claimed invention is not enabled.

Applicant is invited to provide evidence in the form of data or 132 declarations to support a transcriptional factor activity of SEQ ID NO: 35 in a transgenic plant.

In the event that Applicant is able to obviate the above rejection, the enablement will still be limited to SEQ ID NO: 35 encoding SEQ ID NO: 36.

Applicant has not provided guidance for a nucleotide sequence encoding a

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polypeptide having 80%, 85%, 90% or 95% sequence identity to SEQ ID NO: 36 and having Myb-like transcriptional factor regulatory activity. Applicant has not provided guidance for regions in the full-length sequence of SEQ ID NO: 35 that are required to encode a functional Myb-like protein or the regions in SEQ ID NO: 35 or 36 that would tolerate modifications.

Cao et al (Biochemistry (Moscow) 66(6) 623-627(2001) teach unpredictability inherent in modifying even a single amino acid in conserved region of an AP2 type transcriptional factors can change function activity of the protein (Abstract on page 623).

Therefore, given the lack of guidance, the limited working examples, state of the art, and unpredictability as discussed above, the claimed invention is not enabled throughout the broad scope. See *in re Wands* (858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)).

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

### ***Written Description***

Claims 17-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated polynucleotide from any source comprising a nucleotide sequence encoding a polypeptide having at least 80%, 85%, 90% or 95%

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sequence identity to SEQ ID NO: 36 and having Myb-related transcriptional activity, a vector, recombinant DNA construct, a plant and seed comprising said polynucleotide, and methods for transforming a cell with said polynucleotide. In contrast, Applicant describes SEQ ID NO: 35 encoding 36, and partial cDNAs from other plant sources having no known transcriptional factor activity.

*University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997) states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The claimed invention does not meet the current written description requirements because Applicant has not described a representative number of polynucleotides of the genus of the polynucleotides claimed. Applicant has not described a single transgenic plant with modified phenotype as a result of expressing SEQ ID NO: 35. Since Applicant has not described a single variant encoding a polypeptide having the structural and functional properties as recited in the claims, one skilled in the art would not know from the disclosure that Applicant is in possession of the invention as broadly claimed. Since Applicant has not described the polynucleotide of the claims, expression vectors, plants, seed, and cells comprising the polynucleotide, and methods that employ said

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polynucleotide are similarly not described.

See Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices). See, also *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997).

**Remarks**

No claim is allowed.

**Contact information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

10/1/05

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MEDINA A. IBRAHIM  
PATENT EXAMINER

